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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Report of the Evidence-Based Methodology Workshop on Polycystic Ovary Syndrome - Request for Comments

SUMMARY: The National Institutes of Health (NIH) will place in the docket for public review and comment a report resulting from the NIH Evidence-Based Methodology Workshop on Polycystic Ovary Syndrome, to be held December 3-5, 2012. The purpose of the report is to summarize the workshop and identify future research priorities. The report will be available online beginning December 7, 2012, at <http://prevention.nih.gov/workshops/2012/pcos/default.aspx>.

DATES: Comments on the report will be accepted from December 7, 2012, to January 4, 2013.

ADDRESSES: Written comments must be postmarked by January 4, 2013, and should be sent to the NIH Office of Disease Prevention, ATTN: Paris A. Watson, 6100 Executive Boulevard, Suite 2B03, Bethesda, Maryland 20892. E-mail comments should be sent to prevention@mail.nih.gov by January 4, 2013.

FOR FURTHER INFORMATION CONTACT: To request more information, please contact Paris A. Watson at 301-496-6615 or prevention@mail.nih.gov.

SUPPLEMENTARY INFORMATION: Polycystic ovary syndrome (PCOS) is a common hormone disorder that affects approximately 5 million reproductive-aged women in the United States. Women with PCOS have difficulty becoming pregnant (i.e., are infertile) due to hormone imbalances that cause or result from altered development of ovarian follicles. One such imbalance is high blood levels of androgens, which can come from both the ovaries and adrenal gland. Other organ systems that are affected by PCOS include the pancreas, liver, muscle, blood vasculature, and fat.

In addition to fertility impairment, other common symptoms of PCOS include:

- Irregular or no menstrual periods (for women of reproductive age)
- Acne
- Weight gain
- Excess hair growth on the face and body
- Thinning scalp hair
- Ovarian cysts.

Women with PCOS are often resistant to the biological effects of insulin and, as a consequence, may have high insulin levels. As such, women with PCOS are at risk for type 2 diabetes, high cholesterol, and high blood pressure. Obesity also appears to worsen the condition. Costs to the U.S. health care system to identify and manage PCOS are approximately \$4 billion annually; however, this estimate does not include treatment of the serious conditions associated with PCOS.

For most of the 20th century, PCOS was a poorly understood condition. In 1990, the NIH held a conference on PCOS to create both a working definition of the disorder and diagnostic criteria. The outcome of this conference, the NIH Criteria, served as a standard for researchers and clinicians for more than a decade. In 2003, a consensus workshop in Rotterdam developed new diagnostic criteria, the Rotterdam Criteria. The 2012 NIH Evidence-Based Methodology Workshop on PCOS seeks to clarify:

- The benefits and drawbacks of using the Rotterdam Criteria;
- The condition's causes, predictors, and long-term consequences;
- The optimal prevention and treatment strategies.

The NIH workshop is sponsored by the Office of Disease Prevention and the Eunice Kennedy Shriver National Institute of Child Health and Human Development. A multidisciplinary steering committee developed the workshop agenda. The NIH Library created an extensive, descriptive bibliography on PCOS to facilitate workshop discussion. During the two-and-one-half-day workshop, invited experts will discuss the body of evidence and attendees will have opportunities to provide comments during open discussion periods. After weighing the evidence, an unbiased, independent panel will prepare a report that summarizes the workshop and identifies future research priorities.

The report will be available online beginning December 7, 2012, at
<http://prevention.nih.gov/workshops/2012/pcos/default.aspx>.

Dated: November 16, 2012

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